EVALUATION OF INDUCTION OF LABOUR WITH CERVIPRIME GEL VERSUS OXYTOCIN IN PROM

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BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled **"EVALUATION OF INDUCTION OF LABOUR WITH CERVIPRIME GEL VERSUS OXYTOCIN IN PROM "** is bonafide record work done by **Dr. P. NALINI** under my direct supervision and guidance, submitted to the Tamil Nadu Dr. M.G.R. Medical University in partial fulfillment of University regulation for MD, Branch II – Obstetrics & Gynaecology.

Dr.Revathy Janakiram. M.D.,D.G.O.,

Professor & Head of the Department
of Obstetrics & Gynaecology,
Madurai Medical College
Madurai.

DECLARATION

I **Dr. P. NALINI** solemnly declare that the dissertation titled **"EVALUATION OF INDUCTION OF LABOUR WITH CERVIPRIME GEL VERSUS OXYTOCIN IN PROM"** has been prepared by me. I also declare that this bonafide work or a part of this work was not submitted by me or any other for any award, degree, diploma to any other University board either in India or abroad.

This is submitted to The Tamilnadu Dr. M. G. R. Medical University, Chennai in partial fulfillment of the rules and regulation for the award of MD. degree Branch – II (Obstetrics & Gynaecology) to be held in March 2008.

Place : Madurai **Dr. P. NALINI**

Date :

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CONTENTS

INTRODUCTION

The amniotic fluid and the chorioamnion which form the bag of membranes aids in accomplishing the safe journey of the foetus. The amnion at term is a tough, tenacious and pliable membrane which is avascular and derived from the ectoderm. Amniotic fluid arises from both maternal and foetal side which is replaced every 3 hours. At term it measures around 600-800 ml. It functions as a shock absorber, maintains even temperature and allows free movement of the foetus. The chorioamnion acts as a barrier for the pathogens present in the vagina. Spontaneous rupture of membrane most often occurs during the course of active labour.

1. Premature rupture of membrane (PROM) is defined as spontaneous rupture of the chorioamnion before the onset of uterine contraction.
2. Rupture of membrane after 37 completed weeks is PROM
3. Rupture of membrane before 37 weeks is preterm PROM
4. The incidence of PROM is 4-18% at term. Infection closely associates either as an aetiological factor or an important sequence of PROM.

Management of PROM at term remains controversial. Management of PROM, not in labour is best managed by individualized approach. The different modes of management are either expectant management or induction of labour. The standard practice for dealing with PROM at 37 weeks or more has been to induce labour within 6-12 hours after the rupture of membranes if the patient is not in labour . The rationale for this approach is to prevent chorioamnionitis that is associated with high maternal & perinatal morbidity and mortality.

Newborn at term has increased chances of sepsis and increased need for neonatal resuscitation at delivery.

Induction of labour in PROM, not in labour has advantage over expectant management.

In this study we compared the safety & efficacy of prostaglandin E2 Gel administered in endocervical canal with that of intravenous oxytocin infusion for labour induction in PROM.

AIM OF THE STUDY

1. To compare that efficacy and safety of Prostaglandin E2 gel with intravenous oxytocin for induction of labour in prelabour rupture of membrane.

2. To compare the mode of delivery and induction to delivery interval between both groups.

3. To compare the neonatal outcome and immediate puerperal problems between both groups.

REVIEW OF LITERATURE

1. A study conducted by Goeshchen K et al in Department of O.G. Germany, in term PROM patients for induction of labour with endocervical ceviprime gel 0.5mg Vs. intravenous oxytocin infusion was made. The clinical outcome of labour, interval between the PROM to delivery, the incidence of operative delivery and neonatal outcome were compared. 579 women in this study group were divided into two groups. The clinical outcome was significantly better in the PGE2 treated patients. No adverse effects on the neonate was observed.

2. A study conducted by Mahmood TA, in Department of OG, UK which compared the conservative line of management Vs intravaginal PGE2 gel in term PROM cases and studied the main outcome of PROM to delivery, Oxytocin augmentation, mode of delivery, maternal and neonatal infective morbidity. There is significant reduction in the PROM to delivery interval in women managed actively with PGE2 gel and fewer women required oxytocin augmentation. (31% Vs 51%). No significant difference was noted in the infective morbidity and caesarean section rate.

3. A study conducted by Tan BP, Hannah ME, compared prostaglandin Vs Oxytocin for PROM cases at term. Early stimulation of uterine contraction with prostaglandin with or without oxytocin Vs. Oxytocin alone was made. Eight trials were included. Based on three trials, prostaglandin compared to oxytocin were associated with increased risk of chorioamnionitis and neonatal infection. Based on four trials, prostaglandin were associated with decreased need for epidural analgesia. Caesarean section rate, endomertritis and perinatal mortality were not significant in both groups.

4. In Meikel et al study, conducted in Department of O&G, Denvar, in patients with term PROM, the rate of endometritis, clinical chorioamnionitis, caesarean delivery, neonatal sepsis were analysed. The caesarean rate was 12%, Chorioamnionitis 6.8%. Neonatal complications were limited to only 2 cases. The neonatal sepsis occurred in patients with rupture of membranes for more than 24 hours. They concluded higher rate of vaginal delivery and low rate of maternal and neonatal complication, from their study.

5. The study conducted in the Department of OG, Ramathibodi hospital, Thailand, by Herabutya et al, compared intravenous oxytocin with or without 3mg intravaginal PGE2 in term PROM cases. There was no statistically significant difference between the two treatment groups in induction to delivery interval.

6. Arulkumaran et al, conducted a randomized comparison of vaginal prostaglandin gel vs oxytocin infusion for stimulation of labour at term for PROM. The trial showed reduced requirement of epidural analgesia, increased incidence of chorioammionitis with vaginal prostaglandin (Tan & Hannah 2000). The perinatal morbidity and mortality and caesarean section rate were similar. In a women the term PROM, PGE2 and oxytocin were equally effective for induction of labour.

7. A study conducted in Department of OG in NRS college, Kolkatta by Chaudhuri Snahamay et al, which compared the immediate induction with 0.5mg intravaginal PGE2 gel and delayed induction with IV oxytocin in term PROM cases. Mode of delivery, labour characteristics and neonatal and maternal morbidity were compared between both groups. 91% required single application of gel. Immediate induction

with intravaginal PGE2 gel resulted in significantly lower caesarean section rate, (17.8% Vs 28.5%), Low operative vaginal delivery (3.5 Vs 14.2%) in nullipara compared to oxytocin. No significant difference noted in multi para. There is no significant difference in neonatal infection rate in both groups. (2.7 Vs 3.5%).

8. A study conducted by Ekman et al, compared oxytocin with PGE2 gel in cases of PROM with unripe cervix. Cervical priming and labour induction in 20 nulliparus term pregnant women with premature rupture of membranes and unfavourable cervical state was done with intravenous oxytocin for 10 cases and PGE2 gel 4 mg intravaginally for 10 cases. One of the ten women who received oxytocin had a favourable cervical state within 5 hrs, and vaginal delivery within 24 hrs compared to six of the ten women after PGE2 gel application, which was statistically significant. Number of caesarean section was 4 and vaccum delivery was 5 in oxytocin group compared to only 2 vaccum deliveries in cerviprime gel group. They concluded that PGE2 gel was superior to oxytocin for labour induction term PROM.

Premature rupture of membranes is perhaps one of the commonest indication for induction of labour.

Incidence:

Varies from 2.7 to 17% (Lebherz et al 1969, Akthar et al 1980, Singh et al 1990, Sanjal et al 1990). The reported incidence is varied greatly, likely reflecting population demographics, the study type, the study interval, the method of diagnosis, the latency interval and the gestational age at which PROM is diagnosed.

Etiology and pathogenesis:

1. The chorioamniotic membranes possess dynamic properties characteristic of a viscoelastic material. It has the ability to adapt to deformation with recovery due to elastin. Membranes are stressed by internal pressure due to labour, external pressure by trauma or infection which weaken & increase the susceptibility to premature rupture of membranes (Toppozada et al)
2. Infection: It is the major etiologic agent in the pathogenesis of PROM

   Organisms responsible are:

   - Group B streptococcus

- ❖ Bacteroids
- ❖ Gardnerella vaginalis
- ❖ Chlamydia, gonorrhoea

The possible mechanisms are :

a) Activation of phospholipase A2 enzyme & subsequent increase in prostaglandin production which increases the uterine activity & adds stress on the membranes (Bejan et al 1981.)

b) Infection leads to production of proteolytic enzymes & liberation of hydrogen peroxide which results in break down of membranes (Sharra et al 1985).

c) Increase in the lysolecithin due to phospholipase A2 lowers the membrane burst pressure.

3. A local defect at or near the cervix with reduction in type 3 collagen predisposes to membrane rupture.
4. Obstetric factors like multiple gestation & hydramnios predispose to membrane rupture.
5. Sexual activity predisposes to PROM due to bacterial deposition close to the cervical os. Stimulation of uterine activity by

orgasm or seminal prostaglandins could lead to PROM. (Rayburn & Wilson 1980).

6. Low serum levels of ascorbic acid, copper, zinc have been associated with PROM.A strong association between smoking & PROM has been observed (Meyer et al 1977, Naeye et al 1982.)
7. Invasive procedures like amniocentesis, fetoscopy, cordocentesis may result in PROM.
8. Genetic disorders like Ehlers –Danlos syndrome, a connective tissue disorder associated with fragile membrane & hence PROM.
9. Increase in Prolactin level which changes the elastic property of fetal membranes via its effect on the membrane water & electrolyte content predisposes to PROM (Ron et al).

Pathology:

There is thinning of the epithelium at the site of rupture with decrease in tensile strength. Collagen sheets & fibril bundles are dissolved & replaced by amorphous material signifying disorientation of extracellular matrix. Any factor which increases the mechanical stress on that area certainly predisposes to early rupture.

Significance :

Rupture of membranes is of significance for three reasons.

1. If presenting part is not fixed in the pelvis the possibility of cord prolapse & cord compression is increased.
2. Labour may occur shortly.
3. If labour is delayed for >24 hours there is increased likelihood of serious maternal and neonatal infection.

DIAGNOSIS:

Tools reportedly useful in diagnosis of prom

History & examination	**Sonography & dye instillation**
History	Sonography
Observation of leak	Evans blue
Fundal height	Sodium fluorescin
Odour	Methylene blue
	Indigo carmine
	Pyridium

Properties of amniotic fluid

Ferning

pH — litmus

Bromothymol blue

Nitrazine

Diamine oxidase

Microscopy/ Cytologystains

Lanugo

Sudan III

Masson trichome

Papanicolaou

Pinacyanole

Acridine orange

Nile blue sulphate

Vernix cell identification

1. Observation of aminorrhexis:

Diagnosis is made easily when amniotic fluid is in posterior fornix.If no fluid is present slight pressure on the uterus and gentle movement of the foetus may provoke leaking. Otherwise ask the patient to cough or strain. Fluid should be collected over the lower blade of speculum before it comes in contact with the vaginal wall.

2. Nitrazine Test:

The vaginal pH is normally 4.5-5.5. Amniotic fluid usually has a pH of 7-7.5. Nitrazine paper quickly will turn to deep blue if the vaginal fluid has an alkaline pH. The membranes probably are intact if the colour of the paper remains yellow or changes to olive-yellow. Antiseptic solutions, urine, blood & vaginal infections alter the vaginal pH and

cause false positive results. The nitrazine test produces 12.7 % false negative & 16.2% false positive results.

3. Ferning:

Ferning results due to drying out of salts in the amniotic fluid. The sample is placed on a glass slide & allowed to dry, then observed under the microscope looking for a crystallization pattern that resembles a fern. False negative ferning is due to blood or meconium (4.8%), false positive is (4.4%).

4.Evaporation Test:

For the evaporation test, Endocervical sample are heated until the water content has evaporated. If a white residue is left, amniotic fluid is present. If the residue is brown the membranes are intact.

5.Intraamniotic fluorescein:

1ml of a sterile solution of 5% sodium fluorescein is injected in to the amniotic cavity. A tampon is placed in the vagina and examined with long wave ultraviolet light 1 or 2 hr later. The detection of fluorescent material is equivalent to a positive diagnosis of PROM. 1 ml of sterile indigocarmine may be used instead of fluorescein and the tampon is inspected for the presence of blue discoloration.

6.Amnioscopy:

Amnioscopy is an invasive procedure rarely indicated in the diagnosis / management of PROM. It requires a distensible cervix to introduced a metallic or plastic cone for direct visulization of the membrane and the amniotic fluid. Amnioscopy may cause PROM is patients with intact membrane and may carry a large bacterial inoculum in to the amniotic cavity in patients with PROM.

7.Sonography:

Presence of amniotic fluid rules out PROM. Amniotic fluid is measured by four quadrant technique. False positive results can occur in oligohydramnios. Occult loss may be missed as the reduction of amniotic fluid is less. But sonography is not used primarily for diagnosing PROM. Intramniotic instillation of dye is an invasive procedure which is hardly used due to the deleterious effect of dye, infection and missing of meconium stained liquor.

8.Fetal fibronectin:

Fetal fibronectin is a large molecular weight glycoprotein present in large amounts in the amniotic fluid. This substance can be detected in the endocervix or vagina of patients with PROM by means of ELISA. The

test seems to the highly accurate and is not affected by blood. But meconium may interfere.

9.Alta fetoprotein test

AFP is present in high concentration at the amniotic fluid, but does not exist in the vaginal secretion or in the urine. Therefore demonstration of this substance in the vaginal secretion is an accurate test for diagnosis of PROM. A study using a rapid calorimetric monoclonal antibody AFP test found a sensitivity of 98% for AFP ,77% for Nitrazine, and 62% for ferning . Specificity was 100% for AFP test. The test may be unreliable at term because Amniotic fluid AFP decreases with gestational age. Maternal blood contamination affects the accuracy of the test.

10.Diamine oxidase Test:

It is an enzyme produced by decidua, which diffuses into the amniotic fluid. Measurement by a paper strips placed in vagina is an accurate way to diagnose PROM.

11.Microscopic & cytological stains have limited role.

History, nitrazine test, ferning or nile blue staining are usually used to evaluate the presence of membrane rupture. Positive results of any two tests gives an accuracy of about 93%.

COMPLICATIONS

❖ **Maternal complications:**

1. Chorioamnionitis incidence is 9%.It depends on the gestational age of PROM, duration of latent period and amniotic fluid volume. Chorioamnionitis is defined by one of the following signs:

- Two temperature elevations of > than 37.5^{o}C occurring at least 1 hour apart or One temperature elevation of > than 38^{o}C
- Uterine tenderness
- Foetal tachycardia (180/min)
- WBC count >20000 /cu.mm
- Foul smelling amniotic fluid

2.Postpartum endometritis is defined by any one of the following: Fever after delivery (2 temperature elevations >38C occurring at least 6 hours apart not including the first 24 hours)

- Uterine tenderness
- WBC count > 20,000 / cu.mm
- Unhealthy lochia

3.Abruptio placenta:

Incidence is 6%. It is due to progressive decrease in the intrauterine surface area causing detachment.

Foetal Complications

Depends on the gestational age at which PROM occurs

1. Neonatal sepsis: Incidence increases to 1.4% due to PROM.
2. All complications of prematurity in preterm PROM.
3. Lung hypoplasia
4. Foetal deformities
5. During labour chances of cord prolapse, foetal distress is more

MANAGEMENT

After confirming PROM, and gestational age patients who require immediate delivery should be identified. They are:

1. In Labour
2. At Term
4. With foetal distress
5. With congenital anamolies
6. Chorioamnionitis
7. Those who are at high risk for infection like diabetes, heart disease, on immunosuppresants, sickle cell disease.

Management of patients at term or near term

This is controversial, expectant vs. active management. At term 90% of patients will go into spontaneous labour at the end of 24hrs. 38% of patients were not in labour even at the end of 24hrs which increases likelihood of infection to 10%. Studies have shown that active management is cost effective & gives better patient satisfaction.

According to ACOG practice guidelines June 1998 (Level A) Patients who come with term PROM, labour may be induced at the time of presentation or may be observed for 24-72 hours for onset of spontaneous labour. Digital examination should not be performed in whom immediate induction is not planned.

Management of patients with gestational age<32 weeks

Management of these patients is a compromise between maternal infection & pre maturity of the fetus. Expectant management is the mode of treatment.

(According to ACOG practice bulletin (June 1998)

Antibiotics improve the perinatal outcome by reducing the chances of infection. Antenatal steroids are to be administered to reduce the risk of RDS, intra ventricular haemorrhage, necrotising entercolitis, neonatal death. Tocolysis to permit administration of steroids and antibiotics. Digital examination should not be done. Terminate the pregnancy if there are signs of chorioamnionitis.

Management of PROM in gestational age <26 weeks

This group of patients have a very poor perinatal outcome. 48% will deliver within 3 days, 67% with in 1 week, 83% with in 2 weeks. Perinatal mortality is 60-90%. 50% will develop chorioamniotitis, 6.8% will have an abruption & 50% will be delivered by cesarean section. 16% of the surviving newborns will have long term sequelae. If the latency is > 4 weeks there is high risk for fetal musculoskeletal deformities & pulmonary hypoplasia. No plan of management has shown to improve the neonatal outcome.

INDUCTION OF LABOUR

Definition:

Artificial stimulation of uterine contractions before the onset of spontaneous labour with the purpose of accomplishing successful vaginal delivery. Augmentation means enhancing uterine contractions once labour has started. For successful induction cervical ripening is important.

Physiology of cervical ripening:

Progressive increase in gestation or vaginal infection

↓

Increase in cervical hyaluronidase & decreased collagenase inhibitors.Down regulation of estrogen & progesterone receptors.

↓

Increased Interleukin 8 & Interleukin 1 β

↓

Stimulates collagenase & neutrophilic chemotaxis

↓

Enzymatic degradation of extracellular matrix

↓

Increased water content

↓

Decreased collagen concentration & structural rearrangement

↓

Alteration of proteoglycans & glycosaminoglycans ratio

↓

CERVICAL RIPENING

INDICATION FOR INDUCTION OF LABOUR

Maternal indications:

- Abruptio placenta
- PROM
- Chorioamnionitis
- Post term
- PIH, pre eclampsia, eclampsia
- Maternal conditions like diabetes, renal disorder, chronic hypertension

Fetal indications:

- Fetal demise
- Fetal malformation incompatiable with life
- Fetal jeopardy like IUGR

CONTRAINDICATIONS FOR INDUCTION OF LABOUR

Absolute:

- Severe CPD
- Placenta previa III&IV
- Transverse lie
- Previous classical caesarean or myomectomy
- Active genital herpes infection
- Invasive cervical carcinoma
- Pelvic structural deformities.

Relative;

- Grand multipara
- Previous LSCS
- Multiple pregnancy
- Breech
- Poly hydramnios
- Presenting part above inlet
- Maternal heart disease

Pre requisites for induction:

- Establish the indication
- Informed consent
- Pelvic assessment
- Confirmation of gestational age
- Assessment of fetal size & presentation
- Cervical assessment (modified Bishop score)

BISHOP SCORE – In 1964 E.H. Bishop suggested a qualitative pelvic scoring based on 500 pelvic examinations for success of induction.

Factors	0	1	2	3
Cervical Dilatation (cm)	Closed	1-2	3-4	5+
Effacement of cervix (%)	0-30	40-50	60-70	80+
Consistency of cervix	Firm	Medium	Soft	
Position of cervix	Posterior	Mid line	Anterior	
Head station	-3	-2	-1,0	+1,+2

Unfavorable score <6

Favorable score 6,>6

METHODS OF INDUCTION

- Natural methods
- Mechanical methods
- Pharmacological methods

Natural methods:

- Nipple stimulation
- Sexual intercourse
- Enema

Mechanical methods:

- Stripping of membranes
- Balloon catheters
- Lamanaria tents
- Synthetic osmotic dilators
- Amniotomy also known as surgical induction, used for induction & augmentation.

Pharmacological methods;

Drugs commonly used are:

- Oxytocin
- Prostaglandins

OXYTOCIN

Oxytocin is secreted by the posterior pituitary along with ADH. It is an octapeptide and simulates natural labour. Its half life is 2-7 minutes. It is rapidly degraded in the liver & kidney by oxytocinase. Oxytocin binds to oxytocin receptors & increases calcium release from endoplasmic reticulum which increases production of prostaglandin from deciduas to bring about uterine contractions. Oxytocin is responsible for labour contractions through estrogen sensitized receptors and milk

ejection reflex for lactation. Oxytocin was the first polypeptide hormone synthesized in 1953 by Du Vigneaud.

Mode of administration:

Oxytocin is administered as an infusion via infusion pump or by manual counting in isotonic electrolyte solution .A Steady state plasma levels is achieved by 30-40 minutes.

Uses:

- Induction of labour
- Uterine inertia
- Oxytocin challenge test
- Postpartum haemorrhage

Dosage protocols for induction:

Regimen	**Starting**	**Increment**	**Interval**	**Max**
(mU/min)	**Dose (mU/min)**	**dose(mu/min)**	**Min**	**Dose(mU/min)**
Low dose	0.5-1	1	30-40	20
	1-2	2	15	40
High dose	6	6,3,1	15-40	42

Side effects :

- Hyper stimulation –In high dose protocol
- Failed induction
- Uterine rupture
- Hypotension –IV bolus
- Water intoxication
- Neonatal hyper bilirubinemia

RCOG GUIDELINES:

- Oxytocin should be started 4-6 hours following prostaglandins
- In women with intact membrane, do an amniotomy & then start oxytocin
- Minimum possible dose should be used & titrated against uterine contractions.
- Maximum licensed dose is 20mU/min & should not exceed 32mU/min.

PROSTAGLANDINS :

First described by Von Euler and is believed to originate from prostate and seminal vesicle.

They are biologically active derivatives of 20 carbon atom poly unsaturated essential fatty acids that are synthesised from the cell membrane. Prostaglandins are derivatives of prostanoic acid. They are metabolized in the liver and excreted through the kidneys. Prostaglandins have varied actions depending upon the tissue and type of prostaglandin. The probable mechanism of action is alteration of membrane bound Ca++ by inhibiting adenyl cyclase and decreasing the level of intracellular cyclic AMP.

The physiological roles of prostaglandins in female reproductive tract are Ovulation, Sperm transport, Luteolysis, Menstruation, Labour.

Modes of administration:

Intra muscular
Intravenous (not used now)
Oral
Vaginal
Rectal
Sublingual

Uses :

Medical abortion

Cervical ripening before surgical abortion

Induction of labour in second trimester

Cervical priming and induction of labour in third trimester

In prevention and treatment of post partum haemorrhage

Other Uses :

Peptic ulcer

To maintain patency of ductus arteriosus

In glaucoma as second line of drugs

Contraindications :

Absolute :

Hypersensitivity

Asthma

Uterine scar

Relative

Hypertension

CVS disease

Renal disease

Liver disease

Glaucoma

Side effects :

Fever

Nausea, vomiting

Diarrhoea

Bronchospasm

Uterine hyper stimulation

Commonly used prostaglandins are

Prostaglandin E1 (Misoprostol)

Prostaglandin E2 (Cerviprime gel)

Prostaglandin F2 Alpha

CERVIPRIME GEL :

- It is a prostaglandin E2 analogue
- Local application of cerviprime gel used for cervical ripening (ACOG)
- It can be used both intra vaginally and intra cervically.
- Available as 0.5 mg gel.
- Most effective when vaginal pH > 4.5
- Requires refrigeration
- Application should be done in or near the labour ward where uterine activity and fetal heart rate monitoring can be performed.
- Contraction occurs within first 4 hours of application and shows peak activity in the first 4 hours.
- If oxytocin was used for acceleration it should be started after 6 – 12 hrs of the after application.

ACOG recommendations for induction of labour:

Level A : (based on good& consistent scientific evidence)

- Prostaglandin E2 (PGE2) analogues are effective agents for cervical ripening & labour induction .
- Fetal heart rate & uterine activity should be continuously monitored from the time PGE2 vaginal insertion .
- High dose PGE2 vaginal suppository may be used in 2^{nd} trimester fetal demise.
- Misoprostol 25μg every 3-6 hrs is effective for cervical ripening & labour induction.
- With PROM, induction may be done with prostaglandins.
- Either low/high dose oxytocin regime may be used for induction.

Level B (based on limited/ inconsistent scientific evidence)

- Use of misoprostol is to be avoided in women with previous LSCS
- Higher doses of misoprostol are associated with increased risk of uterine hyperstimulation.

Level C (Based on Upon consensus & expert opinion)

- Intra vaginal misoprostol for induction of labour in 3^{rd} trimester with fetal demise
- FHR & uterine activity should be monitored from 30 min to 2hours after prostaglandin administration in live fetus.

MATERIALS AND METHODS

Period of study :

July 2006 to July 2007

Materials and methods :

A total of 100 women with premature of rupture of membrane (PROM) admitted in labour ward Govt.Rajaji hospital were recruited for the study. A detailed history was obtained and a clinical examination and obstetric examination was done. A speculum examination and a vaginal examination was performed. Gestational age was calculated using Naegle's rule and confirmed clinically and by ultrasound. The ripeness of cervix was assessed using modified Bishop's score.

Inclusion criteria ;

1. Primi/ multigravida
2. >37 wks of gestation
3. Cephalic presentation
4. Singleton pregnancy
5. Bishop's score < 6
6. No cephalopelvic disproportion
7. Reassuring CTG

Exclusion criteria :

1. Multiple pregnancy
2. Contraindication to vaginal birth
3. Previous uterine surgery
4. Contraindication to prostaglandins
5. Non reassuring CTG
6. Chorioamnionitis
7. Active labour
8. Preterm premature rupture of membranes

After admission vital parameters like pulse , B.P, temperature was recorded.

All patients underwent an obstetric examination to clinically confirm the gestational age, the lie of the foetus, presentation and the amount of liquor. A speculum examination and vaginal examination was done to confirm the leakage of liquor, colour of liquor, the ripeness of cervix, the presentation and to rule out CPD.

An USG was done in all patients to assess the amount of liquor, placental position, gestational age. CTG was done in all patients.

Before starting on drugs, informed consent was obtained. All the patients were given intravenous antibiotics.

50 patients belonging to group A had PGE2 gel 0.5mg instilled into the endocervical canal. After 6 hours cervical score was assessed. If still unripe a second dose was instilled. If the cervical score was favourable >6 ,labour was augumented with 5units of oxytocin drip, which was titrated to achieve effective uterine contractions.

50 patients belonging to group B were started on i.v oxytocin drip 5units in 500 ml of Ringer lactate. The drip rate was titrated to achieve effective uterine contractions.

In both the groups, labour progress was monitored using a partogram. The parameters monitored were :

Maternal pulse rate, B.P, temperature, Cervical dilatation, station of head, foetal heart rate, drugs given.

If any signs of foetal distress were noted, the patients were taken up for caesarean section. Maternal and foetal outcome and complications were analysed .

Statistical Tools

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2002).

Using this software, frequencies, percentage, mean, standard deviation, x^2 and 'p' values were calculated. A 'p' value less than 0.05 is taken to denote significant relationship.

OBSERVATION

Out of 100, 50 were given cerviprime gel intracervical instillation, 50 were given iv oxytocin.

RESULTS

Table 1 : Age Distribution

Age in years	Cerviprime Gel group		Oxytocin group	
	No	**%**	**No**	**%**
Less than 20	-	-	4	8
20 – 24	20	40	29	58
25 – 29	29	58	15	30
30 & above	1	2	2	4
Total	50	100	50	100
Mean	24.9		23.96	
S.D	2.79		3.51	
'p'	0.1808 (Not significant)			

40% (20/50) of group A and 58% (29/50) of group B were in the age group of 20 to 24 years. 58%(29/50) of group A and 30%(15/50) of group B were in the age group of 25 to 29 years. 0% in group A and 8% (4/50) of group B were in the age group of < 20 years.2%(1/50) of group A and 4%(2/50) of group B were in the age group of > 30 years. There is no statistically significant difference between two groups.

Table 2 : Parity

Parity	Cerviprime Gel group		Oxytocin group	
	No	**%**	**No**	**%**
Primi	30	60	33	66
Multi	20	40	17	34
Total	50	100	50	100
'p'	0.7382 (Not Significant)			

60%(30/50) of group A and 66% (33/50) of group B were primigravidas . 40%(20/50) of group A and 33%(17/50) of group B were multigravidas.There is no statistically significant difference between two groups.

Table 3 : PROM to induction interval

PROM to induction interval in minutes	Cerviprime Gel group		Oxytocin group	
	No	%	No	%
< 120	16	32	12	24
121 – 240	27	54	27	54
241 – 360	6	12	11	22
> 360	1	2	-	-
Total	50	100	50	100
Mean	175.8		176.3	
S.D	80.05		77.9	
'p'	0.7717 (Not Significant)			

The duration of PROM to induction was <2hours in 32% (16/50) of group A and 24% (12/50) of group B .

The duration of PROM to induction was between 2 to 4hours in 54% (27/50) of both groups.

The duration of PROM to induction was 4 to 6 hours in 12% (6/50) of group A and 22%(11/50) of group B.The duration of PROM to induction was > 6 hours in 2% (1/ 50)of group A and 0% in group B.There is no statistically significant difference between two groups.

Table 4 : Bishop Score

Bishop Score	Cerviprime Gel group		Oxytocin group	
	No	%	No	%
3	25	50	10	20
4	19	38	33	66
5	6	12	7	14
6	-	-	-	-

The Bishop's score was 3 in 50 %(25/50) of group A and 20% (10/50) of group B. The Bishop's score was 4 in 38% (19/50) of group A and 66%(33/50) of group B. The Bishop's score was 5 in 12%(6/50) of group A and 14% (7/50) of group B.

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Table 5 : PROM to Delivery interval

PROM to Delivery interval (in minutes)	Cerviprime Gel group		Oxytocin group		'p'
	Mean	**SD**	**Mean**	**SD**	
Primi	602.3	118.9	682.4	91.7	**0.0104 (Significant)**
Multi	539.5	119.8	655	102.6	**0.0048 (Significant)**
Total	577.2	122	673.1	95.4	**0.0002 (Significant)**

The mean duration of PROM to delivery in primigravidas were 602.3 minutes in group A and 682.4 minutes in group B. The mean duration of PROM to delivery in multigravidas were 539.5minutes in group A and 655 minutes in group B. 'p' value was significant in both groups.

Table 6 : Induction to Delivery interval

Induction to delivery interval (in minutes)	Cerviprime Gel group		Oxytocin group		'p'
	Mean	SD	Mean	SD	
Primi	430.5	114.9	507.6	75.5	**0.0034 (Significant)**
Multi	357.8	99.3	475.9	69.3	**0.0004 (Significant)**
Total	401.4	113.7	496.8	74.3	**0.0001 (Significant)**

The mean duration of induction to delivery in primigravidas were 430.5 minutes in group A and 507.6minutes in group B.The mean duration of induction to delivery in multigravidas were 357.8 in group A and 475.9 in group B. 'p' value (0.0001) was significant in both groups.

SECOND GEL REQUIRED :

6% of the patient in cerviprime gel group required second gel which was kept after 6 hours of first gel induction. The efficacy of single dose gel was 94%.

Oxytocin acceleration in cerviprime gel induction group

16% of the patients in cerviprime gel group required oxytocin for acceleration of labour.

Table 7 : Mode of Delivery

Mode of delivery	Cerviprime Gel group		Oxytocin group	
	No	**%**	**No**	**%**
a) Vaginal				
i) Labour natural	40	80	40	80
ii) Outlet	7	14	7	14
iii) LMC	-	-	1	2
b) LSCS	3	6	2	4

In group A 80 %(40/50) were delivered by labour naturale,14%(7/50) were delivered by outlet forceps,6%(3/50) were delivered by caesarean section for non reassuring fetal heart rate with thick meconium.

In group B 80%(40/50) were delivered by labour naturale,14% (7/50) were delivered by outlet forceps. 1 patient was delivered by low midcavity forceps.4%(2/50) of patients were taken up for LSCS foetal distress.

94% of patients were delivered with first dose of cerviprime gel induction. Of which 16% required oxytocin for acceleration.Both instrumental and caesarean section rate were same in both groups.

Table 8 : Apgar score at 1” and 5”

Apgar score at	Cerviprime Gel group		Oxytocin group	
	No	%	No	%
1 minute				
6 / 10	2	4	4	8
7 / 10	31	62	33	66
8 / 10	17	34	13	26
9 / 10	-	-	-	-
‘p’	0.4305 Not significant			
5 minutes				
6 / 10	-	-	-	-
7 / 10	2	4	3	6
8 / 10	31	62	34	68
9 / 10	17	34	13	26
‘p’	0.3534 Not significant			

Apgar score at 1 minute was 6/10 in 4%(2/50) of group A and 8%(4/50) of group B babies. Apgar score at 1 minute was 7/10 in 62%(31/50) of group A and 66%(33/50) of group B babies. Apgar score at 1 minute was 8/10 in 34%(17/50) of group A and 26%(13/50) of group B babies. ‘p’ value was not significant in both groups.

Apgar score at 5 minutes was 7/10 in 4%(2/50) of group A and 6%(3/50) of group B babies.Apgar score at 5minutes was 8/10 in 62% (31/50) of group A and 68%(34/50) of group B babies. Apgar score at 5 minutes was9/10 in 34% (17/50) of group A and 26%(13/50) of group B babies. ‘p’ value was not significant in both groups.

Table 9 : Complications

Complications	Cerviprime Gel group		Oxytocin group	
	No	**%**	**No**	**%**
a) Intra Partum				
Fetal distress	6	12	4	8
Nil	44	88	46	92
'p'	0.7389 Not significant			
b) Post partum				
PPH	2	4	3	6
Nil	48	96	47	94
'p'	0.5 Not Significant			

12% (6/50) of patients in group A and 8%(4/50) of patients in group B were developed foetal distress. None of the patients developed chorio amnionitis. None of the patients developed hyper stimulation.

4%(2/50) of patients in group A and 6%(3/50)of patients in group B developed atonic PPH, which was managed medically.

Table 10 : Neonatal Outcome

Neonatal Outcome	Cerviprime Gel group		Oxytocin group	
	No	**%**	**No**	**%**
Admission HIE 1	5	10	5	10
Admission MAS	-	-	3	6
Not admitted	45	90	42	84
Antibiotic received	-	-	-	-
'p'	0.552 (Not Significant)			

10%(5/50) of newborn in group A and 16%(8/50)of newborn in group B were admitted in neonatal intensive care unit were treated with antibiotics.

90%(45/50) of newborn in group A and 84%(42/50) of newborn in group B had normal Apgar scores and didn't require admission in neonatal intensive care unit.

10% (5/50) in group A and 10% (5/50) in group B were admitted in neonatal intensive care unit for Hypoxic ischemic encephalopathy.

Table 11 : Stay in hospital

Stay in hospital (in days)	Cerviprime Gel group		Oxytocin group	
	No	**%**	**No**	**%**
3 days	40	80	41	82
4 days	7	14	6	12
More than 5 days	3	6	3	6
Mean	3.44		3.36	
S.D	1.21		1.05	
'p'	0.8007 Not Significant			

80% (40/50) of patients in group A and 82%(41/50) of patients in group B were discharged on 3rd day.

14%(7/50) of patients in group A and 12% (3/50) of patients in group B were discharged on 4th day.

6% (3/50) of patients in group A and 4%(2/50) of patients in group B were discharged on 8th day.

DISCUSSION

Prelabour rupture of membranes is a common indication for induction of labour. Clinical management of PROM at term remains controversial. Many investigators believe that prolonged the interval from PROM to delivery is associated with increased incidence of maternal and perinatal infections.

Induction of labour with prostaglandins offers the advantage of promoting both cervical ripening and myometrial contractility in the group of women who present with premature rupture of membrane and an unfavourable cervix.

Common prostaglandins used are PGE1, PGE2. Misopostol is associated with more hyperstimulation and fetal distress. PGE2 induces labour effectively in patients with unfavourable cervix.

Intravenous oxytocin in PROM with unfavorable cervix takes a longer time for induction to delivery. In this study, of 100 patients for induction of labour in term PROM, 50 patients were given iv oxytocin infusion and 50 patients were given PGE2 cerviprime gel endocervically.

1. Age :

In our study, the mean age of the cases in cerviprime gel group was 24.9 years and oxytoin group was 23.96 years. In a study conducted by

Chaudhuri Snehamay et al, the mean age in cerviprime gel group was 23.2 years and oxytocin group was 23.9 years.

2. Parity :

In our study, 63% were primi gravidas, 37% were multigravidas. In the study conducted by Chaudhuri Snehamay et al, 75% were primi gravidas. The study conducted by Kodkany and Telang et al also had greater number of primigravidas.

3. Duration of PROM to induction :

In our study, the duration of PROM to induction was between 2-4 hours in 54% of the cases in both groups. This is in par with the study conducted by Hauth et al which reported duration of PROM to induction was 3 hrs in 59%.

4. Bishop's Score

In the study conducted by Chaudhuri Snehamay et al, the Bishop's score was < 6 in 67.5% of cases in cerviprime gel group and 69.6% in oxytocin group. In our study, the Bishop's score was < 6 in all patients in both groups.

5. Duration of PROM to delivery :

The duration of PROM to delivery in gel group was 10 hrs for primi, 8.9 hrs for multi gravida, the mean was 9.5 hrs. In oxytocin group

PROM to delivery interval was 11.3 hrs in primi, 10.9 hrs in multi, mean was 11.1 hrs which was also statistically significant. The mean latency between the PROM and delivery in the study conducted by Gonen et al, was 15 hr with PGE2 gel, Chaudhuri Snehamay et al, was 17 hrs. In Gonen et al study, they have reported the duration of PROM to delivery to be 30 hrs, with the use of iv oxytocin for induction. But Chauduri Snehamay et al study, oxytocin was started after 12-24 hrs of PROM. The PROM to delivery interval was 21 hrs.

6. Induction to Delivery interval :

In cerviprime gel group, the mean time from induction to delivery was 7.1 hrs in primi, 5.9 hrs in multi with mean duration of 6.6 hrs. In syntocinon group it was 8.4 hrs in primi, 7.9 hrs in multi, with mean duration of 8.2 hrs. they were statistically significant.

The results were comparable with study conducting by Gonen et al (1992). The mean interval between the PG2 gel application and delivery was 6.6 hrs in their study. Another study conducted by Chaudhuri Snehamay et al the mean duration of induction to delivery with PGE2 gel was 8.5 hrs.

In our study in the cerviprime gel group, 94% delivered in a single application. Of which, 16% required oxytocin for acceleration. This was

similar to the study conducted by Gonen et al, who reported that 93% delivered after a single application of PGE2 gel. In Chaudhuri Snehamay et al study, they have reported 91.8% success rate. Ben Haroush et al reported 80% success rate with induction by vaginal instruction of PGE2 tablet.

7. Mode of Delivery :

The rate of cesarean section in our study was 6% for cerviprime gel group and 4% for oxytocin group. A randomized control study conducted by Hannah et al they found there is no significant difference in the rate of ceasarean section. The study of induction with oxytocin or prostaglandin for planned management of PROM by Dare et al, reported that there was no significant difference in the mode of delivery.

8. Apgar score :

Apgar score at 1 min was less than 7/10 in 4% of the cases in group A, compared to 8% in oxytocin group. This is comparable with the study conducted by Chaudhury Snehamay et al, which reported the Apgar score at 1 minute to be less than 7 in 5.4% of cases in gel group Vs 7.1 % in oxytocin group.

None of the babies in either group had Apgar score less than 7/10 at 5 minutes in our study and the study conducted by Chaudhury Snehamay

et al. Apgar score at 1 min and 5 min was not statistically significant in the Herabutya et al study. In our study also statistically significant difference was not noted in Apgar score at 1 min and 5 min. Also there was no significant difference in the incidence of fetal distress in both groups.

9. Perinatal outcome :

In Gonen et al study, there was no adverse perinatal outcome. The perinatal outcome was not significant in our study.

10. Maternal Complications :

Severe maternal complications like chorioamnionitis and post partum endometritis was not observed in both groups in our study. Chaudhury Snehamay et al, reported post partum fever in 1.8% of cases in gel group and 0.8% in oxytocin group.

11. Duration of stay in hospital :

The duration of stay in hospital was not statistically significant in both groups.

SUMMARY

This study evaluated the efficacy of PGE2 cerviprime gel for induction of labour in premature rupture of membranes with intravenous oxytocin.

1. 58% of the patients in group A and 30% of the patients in group B belonged to age group of 25-29 years.
2. 60% of the patients in group A and 66% of the patients in group B were primigravidas. 40% of the patients in Group A and 34% of the patients in Group B were multigravida.
3. Premature rupture of membrane to induction in the interval was 2 to 4 hrs in 54% of the cases in both groups.
4. The Bishop's score was less than 6 in all cases in both groups.
5. The mean PROM to delivery interval was 9.5 hrs, with PGE2 gel, 11.1 hrs with oxytocin which was statistically significant. ($p = 0.0002$).
6. The mean induction to delivery interval was 6.6 hrs with PGE2 gel, 8.2 hrs with oxytocin which was statistically significant. ($p=0.0001$).

6% of the cases in ceviprime gel group required a second gel after 6 hrs of induction and 16% of the cases in the same group required oxytocin for acceleration of labour.

7. 94% in the gel group and 96% in oxytocin group delivered vaginally. 6% in the gel group and 4% in the oxytocin group delivered by caesarean section.

8. 1 minute Apgar score was more than 7/10 in 96% of cases in group A and 92% of cases in group B. 5 minute Apgar score was more than 7/10 in all cases in both groups.

9. Fetal distress in gel group was 12% compared to 8% in oxytocin group.

10. 4% of cases in gel group and 6% of cases in oxytocin group had post partum haemorrhage. None of the patients developed chorioamnionitis or hyperstimulation in either groups.

11. 10% of the babies in cerviprime gel group were admitted in NICU for hypoxic ischemic encephalopathy stage I. 10% of the babies in oxytocin group were admitted in NICU for hypoxic ischemic encephalopathy stage I and 6% for meconium aspiration syndrome

12. 80% of the cases in both groups were discharged from hospital after 3 days.

CONCLUSION

1. Prostaglandin E2 gel was more effective and safer in induction of labour, in cases with premature rupture of membranes compared to intravenous oxytocin infusion.
2. Use of PGE2 Gel for induction of labour in premature rupture of membrane significantly reduced the induction to delivery interval compared to intravenous oxytocin.
3. There was no significant difference in the mode of delivery between both groups.
4. There was no significant difference in the neonatal outcome and immediate puerperal problems between both groups.

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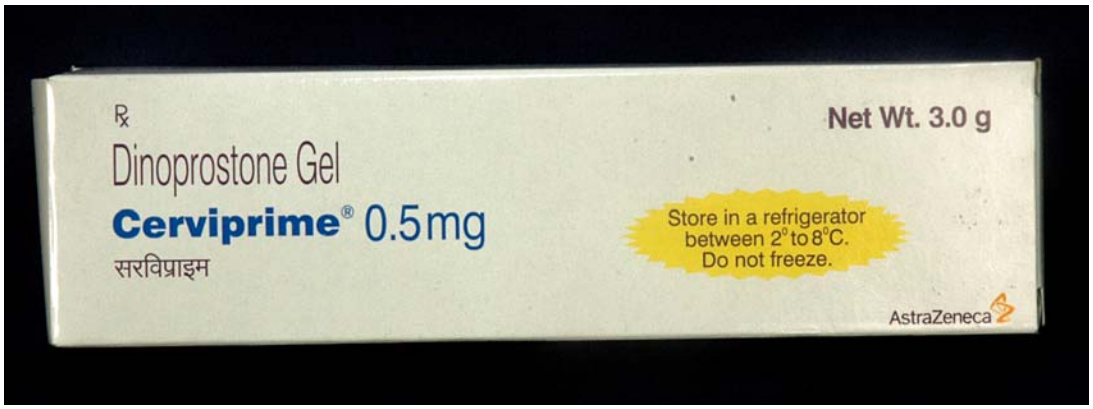
PROFORMA

1. Name:
2. Age :
3. IP no :
4. Obstetric code:
5. Gestational age: LMP: EDD:
6. Ultrasound:
7. Date and time of admission:
8. Date and time of rupture of membranes:
9. Method of confirming rupture of membranes:
    A) Pooling of liquor on speculum examination
    B) Absent membranes
    C) Reduced liquor on USG
10. Bishop's score:
11. Date and time of induction :
12. Method of induction :
    a) PGE2 gel b)oxytocin
    - Repeat gel
    - Oxytocin for augmentation
13. Date and time of delivery :

14. Mode of delivery :
    - labour naturale
    - operative vaginal
    - caesarean
15. Duration of PROM :
16. Duration of induction to delivery :
17. Duration of PROM to delivery :
18. Intrapartum complications:
    i) Hyperstimulation
    ii) Foetal distress
    iii) Chorioamnionitis
    iv) PPH
19. Neonatal outcome
    1. Apgar 1minute
       5minutes
    2. Resuscitation with oxygen
    3. Admission in NICU
    4. Neonatal infection
    5. Neonatal death
20. Duration of stay in hospital

OXYTOCIN

PGE2 GEL


℞
Dinoprostone Gel
Cerviprime® 0.5mg
सरविप्राइम
Net Wt. 3.0 g
Store in a refrigerator
between 2° to 8°C.
Do not freeze.
AstraZeneca

MASTER CHART

MASTER CHART

S.No	IPNo.	Group	Age	Obst. Table	G.A	Colour of Liquor	Bishop's Score	PROM - Induction	PROM - Delivery	Induc- Delivery	II GEL	Syn. Accel.	Intra partum Events	Apgar 1 min	5 min	Neonatal Complication	PP Complication	Stay in Hospital
1	31283	GEL	23	1	38	C	3	420	660	240	No	No	-	7	8	-	-	3
2	31207	GEL	29	2	37	C	4	360	740	380	No	No	-	8	9	-	-	3
3	33508	GEL	23	1	38	C	4	285	685	400	No	No	-	7	8	-	-	3
4	31297	GEL	27	1	38	C	5	310	570	260	No	No	-	8	9	-	-	3
5	33021	GEL	27	2	38	C	4	120	520	400	No	No	-	8	9	-	-	3
6	33824	GEL	24	1	37	C	3	80	540	460	No	No	-	8	9	-	-	3
7	46611	GEL	21	2	38	C	3	135	675	540	No	YES	Fetal Distress	7	8	Admission HIE I	-	8
8	475190	GEL	20	1	38	C	3	180	525	345	No	No	-	7	8	-	-	3
9	48199	GEL	28	2	38	C	4	110	570	460	No	No	-	7	8	-	-	3
10	42744	GEL	26	2	38	C	3	150	485	335	No	No	-	8	9	-	-	3
11	46599	GEL	21	1	37	C	4	150	615	465	No	No	-	8	9	-	-	3
12	44548	GEL	29	2	38	C	3	180	630	450	No	No	-	7	8	-	-	4
13	43546	GEL	21	2	38	C	5	90	375	285	No	No	-	8	9	-	-	3
14	42590	GEL	26	1	37	C	3	150	695	545	No	No	-	7	8	-	-	3
15	45133	GEL	26	1	37	C	3	210	885	675	No	YES	Fetal Distress	6	8	Admission HIE I	-	8

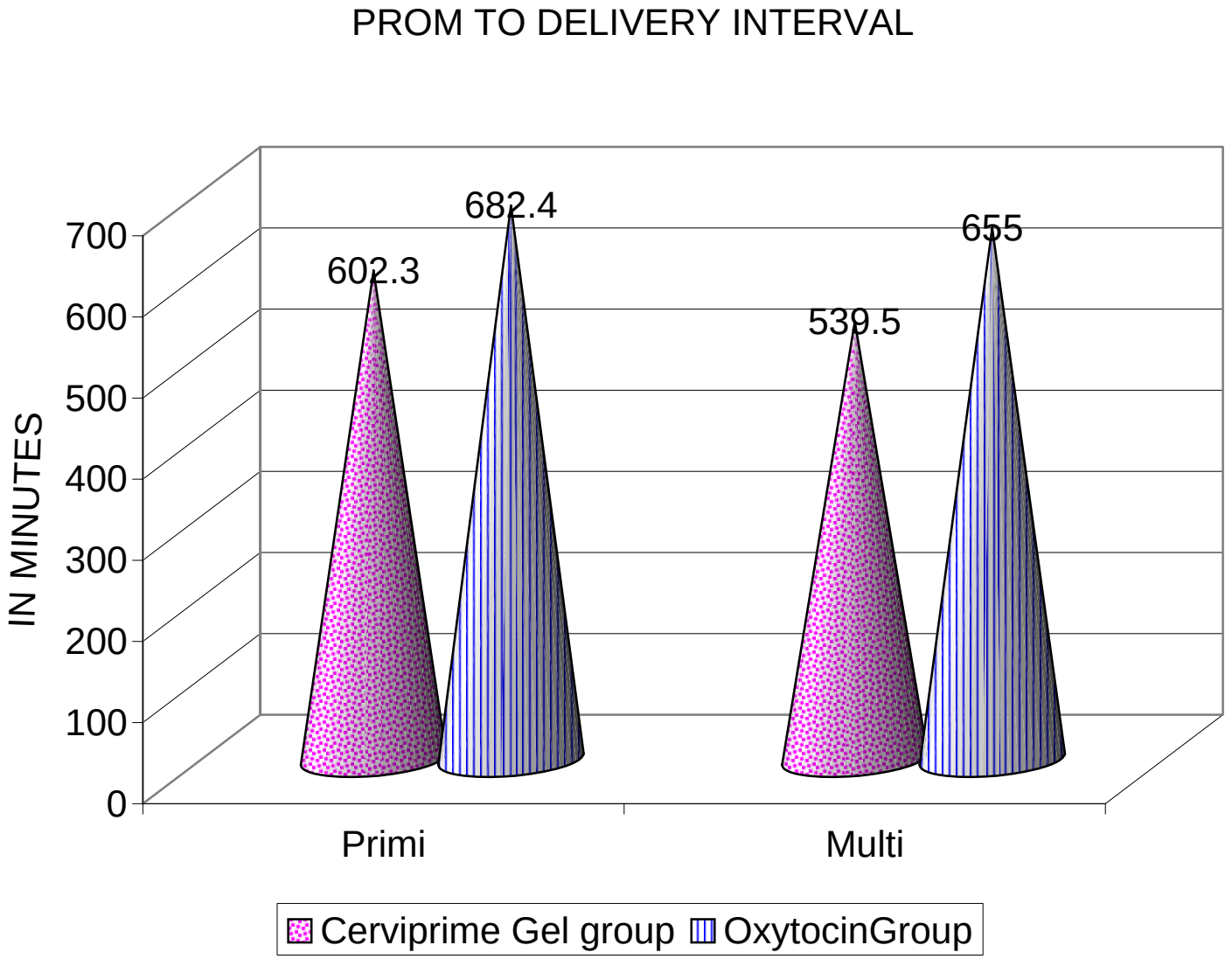
S.No	IPNo.	Group	Age	Obst. Table	G.A	Colour of Liquor	Bishop's Score	PROM - Induction	PROM - Delivery	Induc- Delivery	II GEL	Syn. Accel.	Intra partum Events	Apgar 1 min	5 min	Neonatal Complication	PP Complication	Stay in Hospital
16	44536	GEL	29	1	37	C	4	120	490	370	No	No	-	8	9	-	-	3
17	48205	GEL	22	1	38	C	4	210	750	540	YES	No	-	7	8	-	-	4
18	48470	GEL	26	2	38	C	3	105	490	385	No	No	-	7	8	-	-	3
19	44810	GEL	20	1	37	C	4	210	685	475	No	No	-	8	9	-	-	3
20	46290	GEL	26	1	37	C	4	210	690	480	No	No	-	7	8	-	-	3
21	48640	GEL	22	1	38	C	3	120	665	545	No	No	-	7	8	-	-	3
22	48592	GEL	20	1	38	C	3	89	460	371	No	No	-	7	8	-	-	3
23	54210	GEL	22	2	37	C	3	170	485	315	No	No	-	8	9	-	-	3
24	48581	GEL	24	1	38	C	4	140	645	505	No	No	-	7	8	-	-	3
25	48153	GEL	24	2	38	C	5	150	465	315	No	No	-	7	8	-	PPH	3
26	48205	GEL	22	1	38	C	5	70	520	450	No	No	-	7	8	-	-	3
27	52942	GEL	27	2	38	C	4	120	510	390	No	No	-	8	9	-	-	3
28	53508	GEL	22	1	37	C	4	210	720	510	YES	No	Fetal Distress	6	8	-	-	4
29	51524	GEL	22	1	38	C	3	185	640	455	No	No	-	7	8	-	-	3
30	51070	GEL	26	1	37	C	3	75	490	415	No	No	-	7	8	-	-	3
31	51084	GEL	26	1	38	C	3	210	620	410	No	YES	-	7	8	-	-	4
32	50725	GEL	26	1	37	C	4	185	610	425	No	YES	-	7	8	-	-	3

S.No	IPNo.	Group	Age	Obst. Table	G.A	Colour of Liquor	Bishop's Score	PROM - Induction	PROM - Delivery	Induc- Delivery	II GEL	Syn. Accel.	Intra partum Events	Apgar 1 min	5 min	Neonatal Complication	PP Complication	Stay in Hospital
33	50804	GEL	27	2	37	C	3	180	680	500	No	YES	Fetal Distress	7	7	Admission HIE I	-	4
34	53504	GEL	22	2	38	C	3	210	660	450	No	YES	-	7	8	-	-	3
35	51334	GEL	26	1	38	C	4	135	520	385	No	No	-	7	8	-	-	3
36	53818	GEL	28	2	38	C	4	60	385	325	No	No	-	8	9	-	-	3
37	55842	GEL	28	2	38	C	4	95	405	310	No	No	-	7	8	-	PPH	3
38	55333	GEL	26	1	37	C	3	160	835	675	YES	No	Fetal Distress	7	7	Admission HIE I	-	8
39	52017	GEL	26	1	38	C	4	110	665	555	No	YES	-	7	8	-	-	3
40	55345	GEL	25	1	38	C	5	210	610	400	No	No	-	8	9	-	-	3
41	54410	GEL	21	1	38	C	3	185	410	225	No	No	-	8	9	-	-	3
42	54390	GEL	26	2	39	C	4	240	400	160	No	No	-	8	9	-	-	3
43	55342	GEL	28	2	38	C	5	195	465	270	No	No	-	7	8	-	-	3
44	59669	GEL	25	1	38	C	3	150	390	240	No	No	-	7	8	-	-	3
45	60180	GEL	25	1	38	C	3	90	470	380	No	No	-	7	8	-	-	4
46	61240	GEL	22	1	38	C	3	120	560	440	No	No	Fetal Distress	7	8	Admission HIE I	-	4
47	62797	GEL	28	2	38	C	3	360	765	405	No	YES	-	8	9	-	-	3
48	61263	GEL	28	1	38	C	3	175	448	273	No	No	-	7	8	-	-	3

S.No	IPNo.	Group	Age	Obst. Table	G.A	Colour of Liquor	Bishop's Score	PROM - Induction	PROM - Delivery	Induc- Delivery	II GEL	Syn. Accel.	Intra partum Events	Apgar 1 min	5 min	Neonatal Complication	PP Complication	Stay in Hospital
49	61280	GEL	30	2	37	C	4	310	470	160	No	No	-	7	8	-	-	3
50	62780	GEL	27	2	37	C	3	295	615	320	No	No	-	8	9	-	-	3
51	42575	SYN	22	1	38	C	4	110	630	520	-	-	-	8	9	-	-	3
52	44606	SYN	22	1	37	C	4	140	680	540	-	-	Fetal Distress	7	8	Admission MAS	-	4
53	43787	SYN	23	1	38	C	3	160	670	510	-	-	-	7	8	-	-	3
54	43517	SYN	20	2	37	C	5	120	590	470	-	-	-	7	8	-	-	3
55	44584	SYN	23	2	37	C	4	300	695	395	-	-	-	7	8	-	-	3
56	47907	SYN	29	1	38	C	4	180	675	495	-	-	-	7	8	-	-	3
57	41576	SYN	30	2	37	C	5	35	525	490	-	-	-	8	9	-	-	3
58	48508	SYN	19	1	38	C	4	180	655	475	-	-	-	7	8	Admission HIEI	-	4
59	48850	SYN	20	1	37	C	4	150	675	525	-	-	-	7	8	-	-	3
60	47029	SYN	19	2	38	C	5	150	575	425	-	-	-	8	9	-	-	3
61	48818	SYN	30	2	38	C	4	160	595	435	-	-	-	8	9	-	-	3
62	48518	SYN	24	1	39	C	4	100	790	690	-	-	-	7	8	-	PPH	4
63	48586	SYN	20	1	38	C	4	150	735	585	-	-	Fetal Distress	6	8	Admission MAS	-	4
64	49501	SYN	29	2	37	C	3	80	600	520	-	-	-	8	9	-	-	3
65	49769	SYN	20	1	38	C	4	160	630	470	-	-	-	7	8	Admission HIE I	-	4

S.No	IPNo.	Group	Age	Obst. Table	G.A	Colour of Liquor	Bishop's Score	PROM - Induction	PROM - Delivery	Induc- Delivery	II GEL	Syn. Accel.	Intra partum Events	Apgar 1 min	5 min	Neonatal Complication	PP Complication	Stay in Hospital
66	50145	SYN	29	1	37	C	4	260	710	450	-	-	-	8	9	-	-	3
67	50183	SYN	24	2	37	C	5	150	620	470	-	-	-	8	9	-	-	3
68	54995	SYN	28	2	37	C	4	360	810	450	-	-	-	7	8	-	-	3
69	50550	SYN	22	1	38	C	4	330	925	595	-	-	-	7	8	-	-	3
70	50223	SYN	23	2	38	C	4	120	580	460	-	-	-	7	8	-	-	3
71	50577	SYN	22	1	38	C	4	190	670	480	-	-	-	8	9	-	-	3
72	50710	SYN	23	1	38	C	4	150	645	495	-	-	-	7	8	-	-	3
73	51356	SYN	29	1	38	C	3	120	665	545	-	-	-	7	8	-	-	3
74	50297	SYN	23	1	39	C	5	180	720	540	-	-	-	7	8	-	-	3
75	50245	SYN	24	2	38	C	5	140	555	415	-	-	-	7	8	-	-	3
76	52670	SYN	29	1	38	C	4	255	650	395	-	-	Fetal Distress	6	7	Admission MAS	-	8
77	50518	SYN	29	1	39	C	4	70	550	480	-	-	-	8	9	-	-	3
78	50539	SYN	19	1	37	C	4	190	630	440	-	-	-	8	9	-	-	3
79	51829	SYN	18	1	38	C	5	150	600	450	-	-	-	7	8	-	-	3
80	52061	SYN	23	1	37	C	4	225	685	460	-	-	-	7	8	-	-	4
81	52278	SYN	23	2	37	C	4	300	840	540	-	-	-	7	8	-	-	3
82	52078	SYN	29	1	39	C	4	210	590	380	-	-	-	8	9	-	-	3

S.No	IPNo.	Group	Age	Obst. Table	G.A	Colour of Liquor	Bishop's Score	PROM - Induction	PROM - Delivery	Induc- Delivery	II GEL	Syn. Accel.	Intra partum Events	Apgar 1 min	5 min	Neonatal Complication	PP Complication	Stay in Hospital
83	52386	SYN	23	2	38	C	4	280	700	420	-	-	-	7	8	-	-	3
84	52084	SYN	21	1	38	C	3	210	655	445	-	-	-	7	7	Admission HIE I	PPH	5
85	52284	SYN	23	1	38	C	4	170	635	465	-	-	Fetal Distress	6	7	Admission HIE I	-	8
86	53256	SYN	25	1	38	C	3	135	645	510	-	-	-	7	8	-	-	3
87	53497	SYN	22	1	38	C	4	180	780	600	-	-	-	7	8	-	-	3
88	53290	SYN	22	2	38	C	3	180	810	630	-	-	-	8	9	-	-	3
89	53225	SYN	21	1	38	C	4	275	650	375	-	-	-	7	8	-	-	3
90	53540	SYN	28	2	38	C	3	150	780	630	-	-	-	7	8	-	-	3
91	53844	SYN	29	1	38	C	3	210	615	405	-	-	-	8	9	Admission HIE I	-	3
92	53523	SYN	29	2	38	C	4	50	530	480	-	-	-	7	8	-	-	3
93	54210	SYN	22	1	38	C	4	110	615	505	-	-	-	7	8	-	-	3
94	55951	SYN	28	2	37	C	4	255	675	420	-	-	-	7	8	-	-	3
95	54360	SYN	25	1	38	C	3	30	600	570	-	-	-	7	8	-	-	3
96	54332	SYN	22	1	38	C	4	270	810	540	-	-	-	7	8	-	-	3
97	53970	SYN	23	1	37	C	3	330	1000	670	-	-	-	6	8	-	PPH	3
98	54436	SYN	21	1	38	C	4	140	675	535	-	-	-	7	8	-	-	3
99	54890	SYN	21	1	38	C	4	50	660	610	-	-	-	7	8	-	-	3
100	54321	SYN	26	2	38	C	4	215	655	440	-	-	-	7	8	-	-	3


PROM TO DELIVERY INTERVAL
IN MINUTES
700
600
500
400
300
200
100
0
602.3
682.4
539.5
655
Primi
Multi
Cerviprime Gel group
OxytocinGroup